The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Fiscal Policy

BILL:	CS/CS/SB 1180
INTRODUCER:	Regulated Industries Committee; Health Policy Committee; and Senator Latvala and others
SUBJECT:	Practice of Pharmacy
DATE:	April 17, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.	Kraemer	Imhof	RI	**Fav/CS**
3.	Pace	Hrdlicka	FP	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1180 amends ch. 465, F.S., the Florida Pharmacy Act, to provide that a veterinarian licensed under the Veterinary Medical Practice Act (ch. 474, F.S.) is not prohibited from administering a compounded drug to any animal under the veterinarian's care or dispensing a compounded drug to the animal's owner or caretaker.

The bill creates s. 465.1862, F.S. to define the terms "maximum allowable cost" and "pharmacy benefits manager" and to require certain provisions in pharmacy benefit manager contracts.

There is no fiscal impact to state government.

II. Present Situation:

Veterinary Medical Practice

The practice of veterinary medicine is regulated by the Board of Veterinary Medicine within the Department of Business and Professional Regulation (DBPR).[1] The practice of veterinary medicine includes diagnosing the medical condition of animals and prescribing, dispensing, or

[1] Section 474.204, F.S.

administering drugs, medicine, appliances, applications, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease.[2]

Under the Florida Drug Abuse Prevention and Control Act a practitioner means a licensed[3] physician, dentist, veterinarian, osteopathic physician, naturopath, certified optometrist, or podiatric physician, provided such practitioner holds a valid federal controlled substance registry number.[4] Veterinarians who hold a valid federal controlled substance registry number are authorized to prescribe, administer, dispense, mix, or prepare a controlled substance for use in animals.[5]

Dispensing Practitioner

A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind must register with her or his professional licensing board as a dispensing practitioner, pay a registration fee, and comply with and be subject to all laws and rules applicable to pharmacists and pharmacies.[6] Currently, veterinarians do not register as dispensing practitioners with their professional licensing board (Board of Veterinary Medicine) because veterinarians do not dispense medicinal drugs for human consumption, and the Veterinary Act does not have a corresponding registration requirement.

Veterinarians are not regulated under the pharmacy act. However, veterinarians who dispense medications from an office are subject to dispensing practitioner regulations and inspection by the DBPR.[7]

Compounded Medicine

Compounding is defined as the practice of combining, mixing, or altering the ingredients of one or more drugs or product to create another drug or product.[8] Compounding includes the preparation of:

- Drugs or devices in anticipation of prescriptions based on routine, regularly-observed prescribing patterns;
- Drugs or devices, pursuant to a prescription, that are not commercially available; or
- Commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner. [9]

[2] Section 474.202(9), F.S.
[3] A physician licensed pursuant to ch. 458, F.S., a dentist licensed pursuant to ch. 466, F.S., a veterinarian licensed pursuant to ch. 474, F.S., an osteopathic physician licensed pursuant to ch. 459, F.S., a naturopath licensed pursuant to ch. 462, F.S., a certified optometrist licensed pursuant to ch. 463, F.S., or a podiatric physician licensed pursuant to ch. 461, F.S.
[4] Section 893.02(21), F.S.
[5] Section 893.05(1), F.S.
[6] Section 465.0276(2), F.S.
[7] Section 465.0276(3), F.S.
[8] *See* s. 465.003(18), F.S.
[9] Rule 64B16-27.700(1), F.A.C.

The practice of compounding medications has evolved and expanded to include compounding for office use. Office use is not currently defined in Florida law, but is defined by rule as the providing and administering of a compounded drug to a patient in a practitioner's office or in a health care facility, such as a hospital, ambulatory surgical center, or pharmacy.[10] The rule authorizes a pharmacist to dispense[11] a quantity of a compounded drug to a practitioner for office use by the practitioner provided that the compounded drug is administered[12] to the patient and may not be dispensed to the patient or sold to any other person or entity.[13]

Regulation of Compounded Medicine

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (Pharmacy Act).[14] The practice of pharmacy includes compounding, dispensing, and consulting concerning a medicinal drug. Only licensed pharmacists, or other persons licensed under ch. 465, F.S. may dispense medicinal drugs, except that a practitioner authorized to prescribe drugs may dispense drugs to her or his patients in the regular course of practice.[15] The Pharmacy Act makes no distinction between the dispensing of drugs for human patients and animal patients.

The federal Food and Drug Administration (FDA) traditionally regulates the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. Federal rules currently require that compounded medications be modified versions of the FDA-approved medication.[16] Compounded drugs are not approved by the FDA. The FDA states that, in general, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding.[17]

Regulation of Compounding Medicine for use in Animals

Currently, administering and dispensing compounded drugs to animals or their caretakers is not specifically addressed by state or federal law. However, the practice of veterinary medicine includes the treatment of whatever nature to prevent, cure, or provide relief of a wound, fracture, bodily injury, or disease of an animal.

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[10] Rule 64B16-27.700(3), F.A.C.
[11] Dispensing is the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer, or one who represents that it is his or her intention not to consume or use the drug, but to transfer it to the ultimate consumer or user for consumption by that person. *See* ss. 465.003(6) and 893.02(7), F.S
[12] Administering is the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal. *See* ss. 465.003(1) and 893.02(1), F.S.
[13] *Id.*
[14] Chapter 465, F.S.
[15] Section 465.0267(1), F.S.
[16] 21 U.S.C. s. 353a(b)(3)
[17] U.S. Food and Drug Administration, *Compounding and the FDA: Questions and Answers,* available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited April 16, 2015).

The FDA has issued compliance policy guidance[18] intended to provide guidance and instructions to FDA staff, the industry, and the public regarding the compounding of drugs for use in animals. This guidance describes how the FDA intends to address the issue, including what types of compounding might be subject to enforcement action. The FDA's policy is that it will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals.

Regulation of Pharmacies and Pharmacy Benefits Management Companies

The Board of Pharmacy adopts rules to implement provisions of the Pharmacy Act and takes other actions according to duties conferred upon it.[19] Each pharmacy is subject to inspection by the DOH and may be disciplined for violations of applicable laws and rules relating to a pharmacy.[20]

A pharmacy benefits manager (PBM) administers the prescription drug part of a health plan on behalf of the plan sponsor, self-insured employers, insurers, and health maintenance organizations. Currently, PBMs are not subject to regulation in Florida. Some states, such as Connecticut, Georgia, Kansas, Louisiana, Maryland, and South Dakota, require PBMs to either register with state insurance regulators or be licensed as third-party administrators.[21]

Although PBMs are not subject to licensure in Florida, a PBM may obtain accreditation from various accrediting bodies that determine if certain national standards are met. Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an accrediting body to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards.

Pharmacy Benefits Managers

PBMs negotiate with retail pharmacies to obtain various discounts on prescription drug prices. PBMs can provide the following services to its customers:

- Pharmacy claims processing;
- Mail-order pharmacy services;
- Rebate negotiations with drug manufacturers;
- Development of pharmacy networks;
- Formulary management;[22]
- Prospective and retrospective drug utilization reviews;
- Offer incentives to plan participants to use generic drug substitutions; and
- Disease management programs.

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[18] U.S. Food and Drug Administration, Compliance Policy Guidance, Sec. 608.400, *Compounding of Drugs for Use in Animals,* available at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm (last visited April 6, 2015).

[19] Sections 465.005 and 465.022, F.S.

[20] Sections 465.015 and 465.016, F.S.

[21] Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers,* Business Insurance (August 22, 2010), *available at* http://www.businessinsurance.com/article/20100822/ISSUE07/308229997 (last visited April 15, 2015).

[22] A list of drugs that a health plan uses to make reimbursement decisions.

The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies.

Maximum Allowable Cost Pricing List

Contracts between a PBM and health plan sponsors specify how much the health plan sponsors will pay the PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[23] for brand-name drugs and at a maximum allowable cost (MAC)[24] for generic drugs, plus a dispensing fee. The MAC represents the upper limit price that a plan will pay or reimburse for generic drugs. A MAC pricing list creates a standard reimbursement amount for identical products, and is a common cost management tool developed from a proprietary survey of wholesale prices in the marketplace, taking into account market share, inventory, reasonable profits margins, and other factors. The purpose of the MAC pricing list is to ensure that the pharmacy is motivated to seek and purchase generic drugs at the lowest price in the marketplace.

The federal Medicare Part D program and 45 state Medicaid programs use some type of MAC price lists to reduce costs.[25] The MAC price lists are used by many private employer prescription drug plans for retail generic prescriptions.

III. Effect of Proposed Changes:

The bill amends s. 465.0267, F.S. relating to dispensing practitioners. Currently, only licensed pharmacists and practitioners authorized by law to prescribe drugs may dispense medicinal drugs. The bill provides that a veterinarian licensed under the Veterinary Medical Practice Act (ch. 474, F.S.) is not prohibited from administering a compounded drug to any animal under the veterinarian's care or dispensing a compounded drug to the animal's owner or caretaker.

The bill creates s. 465.1862, F.S., relating to pharmacy benefits manager contracts. The bill defines the following terms:

- Maximum allowable cost is the per-unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, but before any application of copayments, coinsurance, and other cost-sharing charges.
- A pharmacy benefits manager is a person or entity doing business in this state who contracts to administer or manage prescription drug benefits to state residents on behalf of a health insurance plan defined in s. 627.6482, F.S.[26]

[23] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[24] Maximum allowable cost is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.
[25] Medicaid Drug Pricing in State Maximum Allowable Cost Programs, Office of Inspector General, OEI-03-11-00640, (August 29, 2013) *available at* https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp (last visited April 15, 2015).
[26] *See* s. 627.6482(6), F.S., which defines that "health insurance" as any hospital and medical expense incurred policy, minimum premium plan, stop-loss coverage, health maintenance organization contract, prepaid health clinic contract, multiple-employer welfare arrangement contract, or fraternal benefit society health benefits contract, whether an individual policy or group policy, but excluding motor vehicle polices for medical payments or personal injury protection, liability insurance supplemental coverage, or workers' compensation.

The bill provides that in each original or renewal contract between a pharmacy benefits manager and a pharmacy must include requirements that the pharmacy benefits manager:

- Update maximum allowable cost pricing information at least every 7 days; and
- Maintain a process to timely eliminate drugs from maximum allowable cost lists, or modify drug prices to remain consistent with pricing data used to formulate maximum allowable cost prices and product availability.

The effective date of the bill is July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Veterinarians who are licensed and practicing under the Florida Veterinary Practice Act, ch. 474, F.S., may administer a compounded drug to any animal under the veterinarian's care or dispense a compounded drug to the animal's owner or caretaker without concern that such activities are prohibited by the provisions of the Pharmacy Act, ch. 465, F.S., or the rules adopted thereunder.

Pharmacies and pharmacy benefits managers must absorb the cost of verifying that their contracts or contract renewals include provisions requiring updated maximum allowable cost pricing information at least every 7 days and adoption of procedures that will either eliminate drugs from MAC lists or modify drug prices to remain consistent with pricing data used to formulate prices and product availability within a timely manner.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.0276 of the Florida Statutes.

This bill creates section 465.1862 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Regulated Industries on April 15, 2015:
The CS amends s. 465.0276, F.S., respecting dispensing practitioners, to provide that veterinarians who are licensed and practicing under the Florida Veterinary Medical Practice Act, ch. 474, F.S., may administer a compounded drug to any animal under the veterinarian's care, or dispense a compounded drug to the animal's owner or caretaker. The CS removes the exception stating that licensed veterinarians engaging in activities allowed by the Veterinary Medical Practice Act are not limited by the provisions of ch. 465, F.S., the Pharmacy Act, or any adopted rules.

The CS creates s. 465.1862 to define the terms "maximum allowable cost" (MAC) and "pharmacy benefits manager" (PBM) and to require certain provisions in contracts between a pharmacy and a PBM. The CS requires a PBM to update pricing information weekly, and to adopt procedures that will timely either eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

CS by Health Policy on March 23, 2015:
The CS removes the new definition for office use compounding and the new provision stating that nothing in the chapter or rule prohibit a veterinarian from dispensing a compounded drug to an animal patient or its owner or caretaker. Instead, the CS provides that neither the Florida Pharmacy Act nor pharmacy rules limit a veterinarian from engaging in an activity allowed under the Veterinary Practice Act.

B. Amendments:

None.